DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention]this invention was provided with the extracorporeal circulation device of blood, and the function which controls a circulation state especially -- simple -- low -- it is related with an invasion extracorporeal circulation device.
[0002]
[Description of the Prior Art]In the operation of the heart and a large artery, in order to change the heart temporarily into the state near a stop or a stop and to make the function of the heart and a lung take over with machinery, an extracorporeal circulation device is used. The extracorporeal circulation device currently used conventionally is composition which was provided with the blood removal pipe 2, the blood reservoir 83, the heat exchanger 5, the main pump 86, the artificial lung 7, the filter 9, and the blood transfusion pipe 10, and has arranged those elements one by one all over blood circuits as main elements, as shown in drawing 8.
[0003]The blood removal pipe 2 is inserted in the patient's 1 up-and-down vena cava and right atrium, and in order to take many flows, a thick thing is used as much as possible. As for the blood reservoir 83, many open sand molds with which blood touches air are used.
By fall blood removal which used the fall of the blood reservoir 83 with the patient 1, blood flows through a blood removal pipe.
Although it is a small number, the blood reservoir of the enclosed type with which blood does not touch air is also used, and there are some into which blood flows through a blood removal pipe by compulsive blood removal using a blood pump. In the blood reservoir of an open sand mold, since a risk of sending in air in a circuit will increase if the blood volume which stored liquid falls, there are some which emit an alarm, but what adjusts capacity actively is not known. The heat exchanger 5 is installed in a blood reservoir in many cases, carries out perfusion of the fluid (usually tap water) warmed thru/or cooled by metal tubes with the heating-cooling equipment 4, and warms thru/or cools blood. A roller pump or a centrifugal pump is used and the main pump 86 is installed downstream from the blood reservoir. The example currently installed upstream of the blood reservoir does not have a main pump. The whole extracorporeal circulation device is large-sized, and needs to secure a large space compared with a general operation. It is not suitable for carrying for large-sized machinery, and is always installed in the space undergoing an operation.
[0004]Operation of an extracorporeal circulation device is performed by stationing the special staff for it. Although an extracorporeal circulation engineer takes on the duties, a medical practitioner may usually perform an extracorporeal circulation operator. Anyway, the special staff who acquired advanced art is required. An extracorporeal circulation operator is located beside an operating table, does not join operation or is never located in a remote place. The extracorporeal circulation operator is performing adjustment of the capacity of a blood reservoir, or a pump flow rate by manual operation in consideration of the optimum

extracorporeal circulation blood flow rate, looking at the grade of blood removal, and a living body's arterial pressure. Therefore, an extracorporeal circulation operator cannot separate from an extracorporeal circulation device during extracorporeal circulation enforcement.
[0005]By the way, in order to utilize a human and economical medical resource effectively, in the surgery field, the no-touch isolation technique is introduced positively. The no-touch isolation technique in a cardiovascular surgery field is called MICS (Minimally Invasive Cardiac Surgery; low invasion heart surgery). In MICS, in order to reduce invasion, median sternotomy covering an overall length is not performed, but skin incision is shortened as much as possible. Therefore, the view for exposing the heart is restricted. Therefore, the thin thing from which the blood removal pipe used for an extracorporeal circulation device does not become the hindrance of a view is liked.
[0006]
[Problem(s) to be Solved by the Invention]The main purposes of this invention are to provide the extracorporeal circulation device [operation is easy and] which can also automate operation. moreover -- low -- it is the important purpose that realizing the extracorporeal circulation device which makes invasion extracorporeal circulation possible also accompanies. The issue which this invention tends to solve is explained in full detail below.
[0007]Conventionally [<laborsaving and easy-operationality>], when extracorporeal circulation was required in the heart and a large artery operation, the staff for operating extracorporeal circulation was required. And operation of an extracorporeal circulation device requires the art in which operation is complicated and advanced, and needs to be experienced. Therefore, this invention controls operation mechanically, its operation is easy and simple and an object of this invention is to provide the device which can be saved labor.
[0008]As side effects which <low invasiveness> extracorporeal circulation gives to a living body, inducement of dilution of blood, bleeding by a lot of anticoagulant administration, hemolysis by hematocrasia, or inflammation, the fall of the organ blood flow by an unphysiologic steady flow, etc. are mentioned. In order to decrease these side effects, the extracorporeal circulation device which can realize low invasiveness is desirable. On the other hand, since the blood removal pipe used by MICS etc. is thin, the suitable amount of blood removal may not be obtained. Therefore, an object of this invention is to provide the device which can secure the blood flow rate which flows through a circulation system, although low invasiveness is secured.
[0009]<Safety> Since the conventional extracorporeal circulation device is not fully equipped with the security apparatus, it depends for safety on the skill of the engineer who mainly operates extracorporeal circulation. Therefore, an object of this invention is to provide a hardware target or the device provided with the security apparatus by software.
[0010]The extracorporeal circulation device of the <secured of miniaturization and portability> former is large-sized, and needs to secure a large space. Movement is difficult and it has interfered with elastic employment of equipment. Therefore, this invention aims at a miniaturization and a mobile improvement of a circulation system.
[0011]
[Means for Solving the Problem]In order to solve the above-mentioned technical problem, an extracorporeal circulation device of this invention is provided with the following.
It is the extracorporeal circulation device constituted so that a predetermined element might be arranged and extracorporeal circulation of the blood might be carried out into a circuit, and is a blood pump.
A blood reservoir which has a capacity detection means for detecting a capacity regulation means and capacity for fluctuating capacity to store actively.
A control means for controlling a flow of a blood pump, while an output of a capacity detection means is supplied and controlling capacity of a blood reservoir via a capacity regulation means.
It is constituted so that it may be possible to control a capacity regulation means by a control means at least, and to adjust a circulation state in a circuit by it. According to this

composition, according to being able for a blood reservoir to have a capacity regulation means and a capacity detection means, and to control that capacity, operation of a device does not need an operator's advanced art, but will become easy and simple.
[0012]It has preferably a circulation state detection means which detects a circulation state in a circuit, and according to an output which a circulation state detection means detected, a control means constitutes so that a circulation state in a circuit may be adjusted. Thereby, automatic operation becomes easy.
[0013]Let a blood pump be a non-positive-displacement-design blood pump preferably. a blood removal pipe sticks fast by using a non-positive-displacement-design blood pump -- etc. -- can prevent negative pressure excessive at the time of a trouble from occurring, and safety increases, and small -- low -- it is possible to build an invasion system.
[0014]A blood chamber which stores blood for a blood reservoir, and its blood chamber are preferably considered as composition which has **** external housing. Or a blood chamber which stores blood, pressure control chambers which adjust blood volume in a blood chamber adjoined and provided in the blood chamber, and these two rooms are considered as composition which has **** external housing. In any case, a blood chamber makes it a complete rebreathing system with which the indoor blood does not meet with the open air. By making a blood reservoir into a complete rebreathing system, compulsive blood removal becomes easy from a viewpoint of safety compared with an open sand mold. Therefore, it is also easy to secure a large flow rate and to realize low invasiveness. It becomes easy [a miniaturization]. By changing at least some outer walls of a blood chamber, a capacity regulation means is constituted so that capacity may be adjusted.
[0015]As for a capacity detection means, in these composition, it is preferred to constitute so that blood volume of a blood chamber may be detected based on a deformed state of an outer wall of a blood chamber. Thereby, regulation of capacity and measurement of capacity can be performed with easy composition. It is preferred to form at least a part of blood chamber with a diaphragm which is a flexible septum. While being able to perform capacity regulation and capacity detection with composition easily by pressing or towing a diaphragm with a gas or a fluid according to this composition, shape of a blood reservoir and flexibility of a setting position are high. As for a capacity regulation means, when it has a pusher plate which consists of a hard board and the pusher plate presses or tows a septum, it is preferred to constitute so that capacity of a blood chamber may be adjusted. Thereby, a mechanism for capacity regulation can be simplified and a device can be manufactured cheaply.
[0016]A non-positive displacement type pump installs in a circuit preferably only at the upstream of a blood reservoir. According to this composition, it is easy, and compulsive blood removal by negative pressure can make a blood removal pipe thin, and is advantageous to realization of low invasiveness.
[0017]It constitutes from a pressure sensor in which a circulation state detection means was provided by inflow part preferably. It constitutes so that a circulation state detection means may detect a circulation state based on an output of the consumed electric current and/or a power consumption monitor which were connected to a drive of a blood pump. A circulation state detection means has preferably a circulation state estimation means to presume a living body's arterial pressure and/or an extracorporeal circulation blood flow rate, based on data obtained from the inside of a circuit. According to these composition, excessive negative pressure can be prevented from starting a blood removal pipe, a possibility of drawing air decreases, and safety increases. In composition of detecting a circulation state from the consumed electric current of a blood pump, etc., since a sensor is not needed, a system can be manufactured cheaply.
[0018]Preferably, a control means is controlled to lower number of rotations of a blood pump, or to lower capacity of a blood reservoir, when a blood removal part inhales based on information acquired from a circulation state detection means, **** is detected and it is detected with this ****. It can be coped with easily for a blood removal part sticking fast by that cause, and inhales, **** can be prevented, and safety increases.

[0019]Having a means to set up a preset value which shows a range which serves as a critical value or a target preferably about information acquired from a circulation state detection means, a control means is based on comparison of information concerned and a preset value, and increases or decreases an extracorporeal circulation flow of blood. Preferably, at least by one side of operation which raises number of rotations of a blood pump, or lowers capacity of a blood reservoir, perform an increase in an extracorporeal circulation flow and reduction of an extracorporeal circulation flow, It constitutes so that at least one side of operation which lowers number of rotations of a pump or raises capacity of a blood reservoir may perform. Thereby, automatic operation of extracorporeal circulation becomes easy.
[0020]It has a means to make a circulation system generate pulsatile flow, by making number of rotations of a blood pump fluctuate periodically, or making capacity of a blood reservoir fluctuate periodically preferably. Thereby, suitable organ perfusion is obtained also in a patient who has complication, such as cerebrovascular disease and renal failure.
[0021]Preferably, among elements arranged in a circuit, at least, a blood pump, a blood reservoir, an artificial lung, and a filter are assembled in one, and are constituted. Thereby, portability increases.
[0022]It has an aeration detection means to detect preferably an aeration arranged at an inflow part of a circuit, and a means to perform at least one side among generating of an alarm, and automatic stay of a pump when it operates according to an output of an aeration detection means and mixing of air into a circuit is detected. Thereby, a serious trouble of mixing in a circuit of air can be prevented, and safety increases.
[0023]
[Embodiment of the Invention]Hereafter, with reference to drawings, an outline is indicated about an embodiment of the invention. The extracorporeal circulation device in one embodiment of this invention is shown in drawing 1. Although the same number was attached about the same component as the conventional example of drawing 8, the arrangement is not necessarily the same as that of a conventional example.
[0024]All over the circuit from the blood removal pipe 2 to the blood transfusion pipe 10, the filter 9, the main pump 6, the artificial lung 7, and the blood reservoir 3 are arranged as main elements toward the lower stream from the upper stream (blood removal tubeside), and they are connected by the short tube one by one. The drive 38a and the motor for driving 38b are formed in the blood reservoir 3 and the main pump 6, respectively. The circuit internal pressure measurement port 37 which contains a ** sensor in the inflow part (the inflow part said by this invention refers to some blood circuits of the upstream from a main pump) of a circuit, and the ultrasonic flowmeter probe 31 are arranged. 39 is a controller which makes a control means and is connected with the blood reservoir 3, the main pump 6, the circuit internal pressure measurement port 37, and the ultrasonic flowmeter probe 31 by the wiring 40. 11 shows the flow of the blood in a circuit.
[0025]The blood reservoir 3 has a capacity regulation means for fluctuating the capacity to store actively. The drive 38a makes a part of element of a capacity regulation means. Although not illustrated by drawing 1, the blood reservoir 3 has a capacity detection means for detecting capacity. The circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31 are the means for detecting the circulation state in a circuit.
[0026]The controller 39 controls the capacity and the main pump 6 of the blood reservoir 3 according to the output of the circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31. Since the controller 39 holds the reference value for control and performs control based on it, it has a set part for setting up a reference value. Although it is desirable that it is variable as for setting out of a reference value, it may be immobilization depending on the conditions of use. It is not indispensable that control by the controller 39 is automatically performed with the output of the circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31. Even if it is the composition of operating the controller 39 manually, when the blood reservoir 3 has a capacity regulation means, it is because the main part of the effect of this invention is obtained. The main things of the above

elements are explained in full detail below.

[0027]The blood reservoir 3 and the <capacity adjustment> blood reservoir 3 are provided with the following.

The blood chamber 16 which puts in and collects blood as shown in drawing 2.

The pressure control chamber 17 for adjusting the inner capacity of the blood chamber 16.

Both ** 16 and 17 are divided by the existing flexible septum (diaphragm) 18. A communication trunk for 3a and 3b to connect with a circuit and 3c are the communication trunks for connecting the pressure control chamber 17 and a capacity adjustment (not shown). Although not illustrated to drawing 2, it has a capacity detection means which detects the stored blood volume. The blood reservoir 3 can adjust the amount of blood storage actively with a capacity adjustment. The thing of various gestalten can be used as the blood reservoir 3 in this invention, and its capacity adjustment. It explains classifying them.

[0028]The blood reservoir generally built into an extracorporeal circulation circuit has an open sand mold with which air touches blood, and an enclosed type which does not touch air. In the conventional extracorporeal circulation device, the open sand mold reservoir is incorporated in many cases. However, in order to consider it as a simple extracorporeal circulation device, the reservoir of the open sand mold which must always supervise the amount of blood storage of a reservoir is unsuitable. Therefore, in this invention, an enclosed type is preferred. The blood volume of a blood chamber is made to fluctuate actively, and there are a hydrostatic pressure type which adjusts blood volume, and a mechanical cable type which adjusts blood volume second by [direct] carrying out pressure towage of the blood chamber mechanically by carrying out pressure towage of the blood chamber via the first fluid or gas as a capacity adjustment for adjusting.

[0029]In the first hydrostatic pressure type, as shown in drawing 2, two rooms, the blood chamber 16 which puts in blood, and the pressure control chamber 17 which wrap in the whole or a part of blood chamber and into which the gas and fluid for ****** are put, exist. The whole or some of container serves as elasticity, ** of the pressure control chamber 17 is reflected in the blood chamber 16 via the elasticity portion of the blood chamber 16, and, as for the blood chamber 16, the capacity of the blood chamber 16 is adjusted. Drawing 2 shows the blood reservoir which has the existing flexible septum (diaphragm) 18 also in a hydrostatic pressure type.

[0030]A gas or a fluid may be sufficient as the medium of **. If the fluid had mobility, it is [anything] good. Although the deaeration physiological saline from which it sterilized and dissolved gas was removed is preferred, the mere water which has not sterilized since blood is not touched directly may be sufficient. Fluids, such as a fluid and a gas, are sent into a pressure control chamber, and the blood reservoir capacity adjustment made to generate suitable ** may be separately installed via a tube, although including in a blood chamber is also possible. The whole system becomes compact when it incorporates. When it is made separate, the blood chamber itself becomes compact and its restriction of the setting position of a blood chamber decreases.

[0031]A blood reservoir capacity adjustment is [anything which may generate suitable **] good. When a medium is air, it is also possible to use the compressor which can adjust **. When a medium is a fluid, there are a method (capacity regulation method) which specifies capacity, such as a syringe and bellows, directly, and a method (pump fluid pressure control mode) which adjusts fluid pressure using a liquid-sending pump.

[0032]The device of structure as shown in drawing 3 can be used for a capacity regulation method. The figure (a) shows the device which specifies the capacity of a pressure control chamber using the piston 19. The pressure adjusted by the position of the piston 19 is transmitted to the pressure control chamber 17 via the communication trunk 19a. As for the Drawing (b), (c), and (d), capacity is respectively adjusted with the syringe 20, the bellows 21, and the pusher plate 22. It is respectively connected to the pressure control chamber 17 via the communication trunks 20a, 21a, and 22a like (a). The piston 19, the syringe 20, the bellows 21, and the pusher plate 22 are driven by a motor etc.

[0033]In a pump fluid pressure control mode, the capacity of a pressure control chamber is adjusted using the liquid-sending pump for blood reservoir capacity adjustments. The pump used here is [anything] applicable if liquid sending is possible. As performance called for, it is small and what is excellent in reliability and endurance, is excellent in a response, and can generate high ** regardless of the direction of liquid sending, and cost does not require is good. Specifically, a centrifugal pump, a mixed flow pump, an axial flow pump, a friction pump, a gear pump, a roller pump, etc. are mentioned. The switching valve into which a centrifugal pump and a mixed flow pump change a direction since the direction of liquid sending is one way is needed. Drawing 4 (a) and (b) shows the example which used the roller pump 23 and the axial flow pump 24, respectively. In a figure, 25 is a liquid-storage room for liquid sending.

[0034]As the second mechanical cable type, composition as shown in drawing 5 can be used. In this case, a blood reservoir capacity adjustment becomes the structure coupled directly with the blood chamber. Drawing 5 (a) is the example which used the piston 12. The blood chamber 12c serves as a container variable in capacity by the position of the piston 12. 12a and 12b are the communication trunks for connecting with a circuit. The Drawing (b), (c), and (d) shows respectively the example in which capacity is adjusted with the syringe 13, the bellows 14, and the pusher plate 15. As a driving source, a motor, an electromagnet, etc. are used and capacity is adjusted by receiving a certain pressure towage.

[0035]In both the first mechanical cable type and the second hydrostatic pressure type, shape of a blood chamber must be made into what has a few blood-flow **** part in order to improve anti-thrombus nature. It is thought that the direction of a hydrostatic pressure type has little restriction of the design of a blood chamber, and is superior to a mechanical cable type in anti-thrombus nature. On the other hand, since a mechanism is simple, and part mark also have them and it ends, a mechanical cable type can be manufactured cheaply. [few] Although the target patient calls on an adult or a child, if the region of accommodation of blood chamber capacity is an adult, it is desirable for it to be able to adjust to 100 ml - 4000 ml.

[0036]The thing of various gestalten can be used as composition of the capacity detection means which detects the capacity of a blood chamber. If a piston, a syringe, and bellows are used for a blood chamber, capacity is simply detectable with the displacement position of the axis of rotation of a drive motor. The capacity of a blood chamber is measurable also by the method of attaching capacity detection means, such as a hall sensor and an ultrasonic crystal, to a blood chamber or a pressure control chamber, or sending weak current through a blood chamber and measuring impedance and conductance with a current potential plan. When the fluid is liquid in the case of a hydrostatic pressure type, even if it measures the capacity of the liquid discharged via the tube from the regulating chamber with a volume plan, the capacity of a blood chamber can be measured. Since the mensuration of the capacity of the discharged liquid has high flexibility, it can consider many methods, but it is good to measure weight with a weigher simply. The means for supplying detected information is required for the controller 39, and for that purpose, it constitutes so that a detection result may be outputted as an electrical signal, for example.

[0037]It is possible to include a heat exchanger in the blood reservoir in this invention. There are some methods incorporating a heat exchanger and the following is mentioned as an example. Warming of a living body and cooling are possible for blood ****** by installing the tube made with the construction material which was excellent in heat exchange ability in the blood chamber of a blood reservoir in the first place, and carrying out perfusion of the fluid warmed or cooled in the tube. Warming of a living body and cooling are possible for blood ****** by warming or cooling a pusher plate in the mechanical reservoir which used the pusher plate for the second. If it limits only to warming, how to build a heater into a pusher plate will also be considered, and it will be a simple and effective method. Warming of a living body and cooling are possible for blood ****** by warming or cooling the liquid in a pressure control chamber with a hydraulic system reservoir to the third. It is an effective method, also in order to lose the **** part of blood, to think that anti-thrombus nature becomes high and to improve low invasiveness rather than installing a heat exchanger in a blood chamber.

[0038]The <main pump 6>, next the main pump 6 are explained. Since the blood removal pipe used by MICS etc. is thin, the suitable amount of blood removal may not be obtained. Therefore, it is necessary to add the suitable negative pressure which is not excessive to blood removal. Since addition negative pressure has a limit in fall blood removal, the compulsive blood removal using a pump is preferred. In fall blood removal, in order to enlarge a fall, it is necessary to make an operating table high but, and in compulsive blood removal, the same operating table as the general operation of those other than the heart can be used, and it is effective on employment of an operating room.

[0039]Generally, there are a positive-displacement design and a non-positive-displacement design in a liquid-sending pump. The roller pump mostly used to an extracorporeal circulation device is classified into a positive displacement pump. the problem at the time of using a positive displacement pump for the main pump of an extracorporeal circulation device, and moreover installing in the upper stream from a blood reservoir sticks to a blood removal pipe -- etc. -- when the obstacle of a circuit arises, it is that excessive negative pressure occurs in the inflow part of a pump. Excessive negative pressure may damage the body tissue of a blood removal part, and may cause serious troubles, such as drawing in into the circuit of air. for this reason -- sticking fast as a kind of main pump installed in the upper stream from a blood reservoir -- etc. -- the non-positive displacement type pump which excessive negative pressure did not occur at even if it produced, but was excellent in accommodativeness is preferred. The typical things of a non-positive displacement type pump are turbo-pumps, such as a centrifugal pump, a mixed flow pump, and an axial flow pump. Although these all can be used for this invention, since the axial flow pump needs to make number of rotations very high in order to generate high **, if hemolysis and endurance are taken into consideration, it is not desirable selection. Therefore, a centrifugal pump and a mixed flow pump are preferred.

[0040]Control of a circulation state by the controller 39 in <the controller 39 and a circulation state detection means>, next the extracorporeal circulation device of this invention is explained. In order to make operation of an extracorporeal circulation device simple and to automatic-control-ize it most preferably, control by a computer is required. It is also effective in control to consider and combine some methods.

[0041]the 1st method is based on ** -- it sticks fast and they are detection and prevention. That is, if monitor the inlet pressure of a circuit, it inhales from a pressure wave form, **** is detected and inhaled and **** appears, control which lowers the number of rotations of a pump or lowers the capacity of a blood reservoir will be performed. Reflecting venous pressure, if ** of an inflow part is normal, it serves as a steady flow which does not almost have pulse pressure. However, if a blood removal pipe sucks up and **** arises, disorder of the unusual pressure wave form characterized by the rapid fall of ** will arise. This serves as increase of pulse pressure, increase of a pressure change (increase of the absolute value of ********), and change of **********, and appears. The ** sensor of the pressure measuring port 37 which constitutes a circulation state detection means detects this, and the information acquired by it is transmitted to the controller 39 which is a control means. The computer is built into the controller 39, and using the information acquired from the ** sensor, the main pump 6 and/or a blood reservoir are adjusted so that blood may flow through the inside of an extracorporeal circulation device favorably.

[0042]If the 2nd method sets up the lower limit value of inlet pressure and it is less than a preset value, it will be the controlling method which lowers the number of rotations of a pump or lowers the capacity of a blood reservoir. Although a certain amount of [a lower limit value] negative pressure is unavoidable, since it becomes the origin of obstacles, such as cavitation generating of a main pump and drawing in into the circuit of unexpected air, negative pressure which is less than -100mmHg must be prevented. In order to measure the inlet pressure of a circuit as a circulation state detection means like the 1st method also in this case, the ** sensor 37 shown in drawing 1 is used. It is required for the controller 39 to have a means to set up the lower limit value of inlet pressure.

[0043]The 3rd method will be the controlling method which lowers the number of rotations of a

pump or lowers the capacity of a blood reservoir, if measure the consumed electric current or electric power of a blood pump, a blood removal part inhales from the waveform of the consumed electric current or electric power, **** is detected and inhaled and **** appears. Although this is fundamentally the same as the 1st method, in order to use the in-house data which the motor of a pump has, a special sensor is not needed, but it leads to reduction of cost. In this case, since the consumed electric current and power consumption of a drive (motor) which are driving the blood pump must be measured, a means to monitor the current or electric power of a motor of a pump is needed as a circulation state detection means.

[0044]If a living body's arterial pressure and extracorporeal circulation blood flow rate used as a target are set up and both this arterial pressure, this flow, or either is less than a preset value, the 4th method, If pump rotation frequency is raised, or the capacity of a blood reservoir is lowered and both this arterial pressure and this flow exceed a preset value, it will be the controlling method which lowers pump rotation frequency or raises the capacity of a blood reservoir. The arterial pressure and the extracorporeal circulation blood flow rate to set up must be determined according to a living body's individual difference or the condition of the technique and a living body, and cannot consider setting it as the same value in any situations. However, it is possible to decide target arterial pressure suitable for each case and an extracorporeal circulation blood flow rate to be beforehand, and it is not necessary to change a preset value frequently during extracorporeal circulation implementation. It is not especially limited which shall be given priority to and adjusted between pump rotation frequency and blood reservoir capacity, but it is both possible.

[0045]Until it sets up the optimum upper limit (it is described as Arpm) of pump rotation frequency and exceeds Arpm as one desirable method, It controls towards giving priority to blood reservoir capacity, increasing capacity, and considering it as the maximum (full blood removal), and if it will be necessary to exceed Arpm in order to make a blood flow rate increase, how to reduce blood reservoir capacity without raising number of rotations can be considered. Administration of a pressure-up agent or vasodepressor is also required during extracorporeal circulation, and suitable treatment is needed suitably. If a living body's arterial pressure and extracorporeal circulation blood flow rate are measurable as a circulation state detection means provided in an extracorporeal circulation device in the case of the 4th method, a pressure (blood) monitor line, a blood flow merer, etc. which it was not limited in particular, for example, were formed in blood circuits will be mentioned.

[0046]Reduction of the fill ration of an extracorporeal circulation circuit is attained by simplifying a <simplification of circuit and system> circuit and shortening a tube as much as possible. The reduction in a fill ration can be contributed to low invasiveness by suppressing generating of the edema by the hemodilution and reducing the necessity for blood transfusion substantially. By assembling the circuit on the manufacture level beforehand, a labor required for an assembly is omitted and it is connected with human laborsaving and cost reduction. If the restoration in a circuit is also substituted for the manufacture level, preparation further before an operation is mitigable. The conventional extracorporeal circulation device is large-sized, and the large space needed to be secured, and since movement was difficult, it had interfered with elastic employment of equipment. In this invention, a circuit and a drive are designed compactly, it is possible to secure portability and these problems are also solved.

[0047]In the patient who has complication, such as <pulsation and oscillating additional-equipment> cerebrovascular disease and renal failure, the validity of the extracorporeal circulation which has pulsatile flow is accepted. Therefore, also in this invention, it is effective to enable addition of pulsation and vibration, also in order to attain low invasion-ization. The following can be considered to the method of adding pulsation and vibration. It is the method of generating pulsatile flow, by making the number of rotations of a pump 1st fluctuate periodically. It is the method of generating pulsatile flow thru/or vibration, by making the 2nd fluctuate the capacity of a blood reservoir periodically. Especially the latter is the new method which employed efficiently the feature of the blood reservoir that capacity could be adjusted actively. It is also possible to use the 1st and the 2nd method together, and

it is effective.

[0048]Antithrombotic processing is performed to the blood contacting surface of a <anti-thrombus processing> circuit. In this invention, it is a complete rebreathing system which does not touch air, and in order to use the blood reservoir which improved anti-thrombus nature with few blood-flow **** parts, antithrombotic processing and the extracorporeal circulation in conjointly more few anticoagulants become possible. By the usual extracorporeal circulation, anticoagulants, such as heparin, are prescribed for the patient and, specifically, operation of the place which keeps activated coagulation time at 400 seconds or more is enabled in 250 seconds from 200 seconds. As a result, bleeding decreases, and shortening of operation time, the fall of the necessity for blood transfusion, etc. are effective in order to improve the low invasiveness of an extracorporeal circulation device.

[0049]As an example is shown in <separation type navigational panel> drawing 6, the separation type navigational panel 26 which can be installed in a field of operation is used, and operation required for control presupposes that it is possible from a field of operation. The necessity that this provides a special extracorporeal circulation operator decreases, and it leads to human laborsaving. The separation type navigational panel can consider what hung the transparent sterilization covering 27 on the touch-sensitive liquid crystal display. while it installs in the place which the way person's 28 (or the first assistant) hand reaches and the surveillance and control of extracorporeal circulation perform an operation using a sound or a sound -- **** -- a user interface which becomes possible is preferred.

[0050]Operation of <remote control function> extracorporeal circulation will serve as surveillance from remoteness controllable from hand control, if it automates more. If a concrete example is shown, data required for the surveillance and control of extracorporeal circulation will be put on a network by the standards (for example, combination of GPIB and TCP/IP, etc.) of a flexible measuring instrument and communication, and batch management will be carried out at an extracorporeal circulation central control room. Many extracorporeal circulation devices are the effective methods of leading to human laborsaving in the large-scale hospital currently operated simultaneously. Since it becomes possible to record and save all the data, it is useful for scientific practical use.

[0051]An aeration into a <aeration arrester in circuit> circuit is one of the serious troubles which arise during extracorporeal circulation operation. I hear that that it is a simple system has so high safety that it can be used simple, and there is. Some methods can be considered in the ways of coping to an aeration. A bubble detection function is given to the flow instrument the 1st, using an ultrasonic flowmeter as a flow instrument which monitors an extracorporeal circulation blood flow rate. If the probe 31 of an ultrasonic flowmeter is attached to the inflow part of a circuit and a bubble is detected as shown in drawing 1, an alarm will be emitted promptly and it will be coped with.

[0052]The filter 32 is installed in a circuit inflow part the 2nd. The filter 32 is installed in the highest place of a circuit, and it is made for air to accumulate. If the optical sensor 33 for detecting air for an example in the filter 32 as shown in drawing 7 is installed and air accumulates [3rd], this will be detected, an alarm will be emitted promptly and a pump will be stopped. The port 34 for discharging air is installed in the upper tip of the filter 32, and the port 34 is connected [4th] to the suction circuit 35. Usually, this port 34 is intercepted by the breaker 36. If the filter 32 is covered with air, interception of a port will be canceled hand control or automatically promptly, and suction discharging of the air will be carried out outside. It is possible to combine the plurality of these methods or all, and it is effective. 30 in drawing 7 shows the flow of blood.

[0053]Some peripheral equipment is needed for a <linkage with peripheral equipment> extracorporeal circulation device by the technique. That is, they are the reservoir for a suction circuit and suction circuits, a hemoconcentration device (cell SEBA, ultrafiltration equipment), a myocardium protection liquid circuit and a pouring device, a vent circuit, etc. In this invention, it is effective to aim at linkage with these devices.

[0054](Concrete embodiment) The more concrete embodiment which was suitable for below at it as

an example of an operation which uses the extracorporeal circulation device of this invention on the assumption that the mitral valve operation under MICS is described.
[0055]As shown in drawing 1 toward the lower stream (blood transfusion tubeside) from the upper stream (blood removal tubeside) of a <composition of extracorporeal circulation device> circuit, the filter 9, the pump 6, the artificial lung 7, and the blood reservoir 3 are connected by a short tube one by one. These are compact and what has the few amount of filling liquid is preferred. If these are already assembled at the time of shipment, they are convenient. These are preferred, a compact thing and installing in the sterilization field of operation of an operation conjointly can also be sterilized and supplied, and it is effective. If it can install in a sterilization field of operation, the tube for connecting with a blood removal pipe or a blood transfusion pipe can be shortened further, and the whole amount of filling liquid can be lessened further. Capture and interception of the air which mixed the filter in the circuit with removal of the impurity are the purposes. In order to capture air, it installs in the highest position in all the circuits.
[0056]Although its turbo-pump is preferred, if a pump is a small mixed flow pump, it is still more preferred. If sterilization with waterproofness is possible for the motor for driving a pump, it can be installed in a sterilization field of operation, and its handling is convenient. Or handling is still more convenient if it has sterilized by the same product made from disposal as a pump. A compact thing is preferred although anythings can use an artificial lung. Especially the thing that was excellent in gas exchange ability or haemocompatibility is preferred, and its membrane type is better than this point to an air-bubbles type. A blood reservoir measures mechanically the blood volume by which blood storage was carried out, and makes it what can be adjusted. Although various modes can be considered, an example is given about each of a mechanical cable type and a hydraulic system.
[0057]A mechanical cable type uses a pusher plate. The blood chamber of a blood reservoir consists of hard housing and a flexible film. A blood reservoir drive serves as a motor for pressing and towing the hard pusher plate and pusher plate for pressing the flexible film of a blood chamber from a motor controller. The pusher plate must be what can press the flexible film of a blood reservoir uniformly. The load concerning a pusher plate becomes uniform and the direction in which the blood reservoir was installed so that a pusher plate might become level to a floor is preferred. It will warm, if it will be necessary to embed a heater and to raise a patient's body temperature into a PUSHA plate. Although the motor must have a means to change rotation into a straight-line motion, the linear motor which produces a straight-line motion from the start may be used. A motor controller mainly performs position control of a motor. Capacity measurement of a blood chamber is performed by detecting the position of a motor.
[0058]In a fluid pressure type, a flexible septum (diaphragm) is put on the inside of a transparent hard plastic container, and two cavities, a blood chamber and a pressure control chamber, are provided. The pressure control chamber is connected to the liquid-storage room for liquid sending by the connection tube. The pressure control chamber, the liquid-storage room, and the connection tube are filled with the fluid for liquid sending (tap water is used). The roller pump is installed in the middle of the connection tube, by making for Masakata or an opposite direction rotate a roller pump, the capacity of a pressure control chamber is adjusted and, as a result, the capacity of a blood chamber is adjusted. By a fluid pressure formula, what kind of angle may be sufficient as installation of a blood reservoir to a floor, and its flexibility of installation is high. It will warm, if it will be necessary to embed a heater and to raise a patient's body temperature into a pressure control chamber. As shown in drawing 1, the circuit internal pressure measurement port 37 is established in an inflow part, and inflow part circuit internal pressure is monitored. An ultrasonic flowmeter (with bubble detection function) probe is attached to an inflow part.
[0059]The function to make an extracorporeal circulation device generate pulsatile flow is added. Powerful pulsation addition capability is obtained by taking a synchronization periodically and changing the number of rotations of the motor of a pump, and the capacity of a blood reservoir. Different consideration from the conventional extracorporeal circulation

device is required for the connection order foreword of extracorporeal circulation device each component of this invention. Since capture and interception of the air mixed in the circuit are the big purposes, a filter is installed in the style of Mogami. In negative pressure and the lower stream, the upper stream serves as positive pressure from the pump. Therefore, an artificial lung is put on the positive pressure side. If a blood reservoir is the above-mentioned mechanical cable type, it is more desirable to install it in the positive pressure side, although it can install in both negative pressure and positive pressure. If the inside of a blood chamber is positive pressure, it becomes unnecessary for the reason to carry out forcible towage of the pusher plate, and to carry out adhesion fixing of between the flexible film of a blood reservoir, and pusher plates, and it is assembly top convenience. In order to generate pulsatile flow using a blood reservoir, it is desirable to install a blood reservoir downstream most. As mentioned above, it is desirable to become the order of a filter, a pump, an artificial lung, and a blood reservoir from the upper stream (blood removal tubeside) of a circuit toward the lower stream (blood transfusion tubeside).

[0060]There are many functions required for the controller for driving and controlling an extracorporeal circulation device. In this function, it controls with rotation of a pump motor, and control and the drive of a blood reservoir drive motor at least, External data inputs, such as communication with the transducer for inflow part circuit internal pressure measurement, and amplifier, an ultrasonic flowmeter (with a bubble detection function) and a separation type navigational panel and a patient's blood pressure, control of the whole system, etc. are included. An interlocking function with the reservoir for a suction circuit and suction circuits, a hemoconcentration device (cell SEBA, ultrafiltration equipment), a myocardium protection liquid circuit and a pouring device, a vent circuit, etc. is also effective. The input output function of the surveillance and control data through a network is also effective. In order to improve space-saving [of a system], and portability, the small and movable thing of the controller is preferred.

[0061]The filter, the pump, artificial lung, and blood reservoir which constitute the extracorporeal circulation device of <setting of operation> this invention can be installed in a sterilization field of operation by assembling at the time of shipment and making sterilization complete in a short time. Before installing the restoration in a circuit, and air extraction in a sterilization field of operation, they are possible also later. If the silicon film production type lung which a liquid break through does not generate is used, it will be possible to also make it already complete to restoration at the time of shipment, and it will lead to large laborsaving. The port for air extraction is established in the filter and the blood reservoir. An extracorporeal circulation equipment controller is installed near the operating table. Inflow part circuit internal pressure is monitored and the sterilized ultrasonic flowmeter (with bubble detection function) probe is attached. A suction circuit, a myocardium protection liquid circuit, etc. are prepared. Transparent sterilization covering is covered over a separation type navigational panel, and it installs in the place which a way person tends to operate. Extracorporeal circulation is operated under cooperation of a way person, an operation assistant, and an anesthesiologist. Therefore, the special staff only for extracorporeal circulation device operation is not stationed.

[0062]The procedure of the mitral valve operation under MICS using the extracorporeal circulation device of <implementation of operation> this invention is mentioned as an example. Skin incision is shortened as much as possible, the partial median sternotomy is performed, and the heart is exposed. Small incision is added to a right inguinal region, and a femoral artery and vein is exposed. A blood transfusion pipe is inserted in a femoral artery, and a blood removal pipe is inserted in an inferior vena cava from a femoral vein. A blood removal pipe is directly inserted in superior vena cava from a sternotomy part. The double snare on a tape is hung on the right-atrium close relationship of superior vena cava and an inferior vena cava, and it is considered as tourniquet. Interception of this tourniquet must fully be possible so that the compulsive blood removal by the negative pressure of a vein may not draw air, either. Although the thickness of a blood removal pipe changes with patients, insertion is also simple

for a thin thing and it does not become the hindrance of a view. KANYURA for myocardium protection liquid pouring is installed in an ascending aorta. It fills up and the extracorporeal circulation circuit which air extraction ended, and the blood transfusion pipe and blood removal pipe which were attached to the patient are connected. It checks that there is no problem in the whole circuit, and extracorporeal circulation is started.
[0063]Extracorporeal circulation makes automatic operation possible fundamentally. On condition that it is not less than the value which patient arterial pressure set up beforehand, pump rotation frequency is raised until a set flow rate is obtained. If a set flow rate is obtained, the capacity of a blood reservoir will be raised next. As long as patient arterial pressure and a flow allow, the capacity of the blood reservoir is raised. It checks that stable extracorporeal circulation operation is obtained, an ascending aorta is intercepted, myocardium protection liquid is poured in, and the heart is stopped. Myocardium protection liquid, bleeding, etc. which have carried out perfusion are attracted, and are brought together in the reservoir for suction circuits. The collected liquid is processed with hemoconcentration devices (cell SEBA, a ultrafiltration equipment, etc.), and is transfused into a patient. Since operation of a hemoconcentration device is easy, even if it is not the extracorporeal circulation engineer trained specially, it can be enforced.
[0064]Up-and-down vena cava are intercepted and it results in a mitral valve by the right atrium and the atrioseptostomy, or left-atrium incision. Even if the method of a mitral valve operation, for example, mitral valve replacement, and mitral annuloplasty is MICS, it is not different from usual. The air after the end of treatment of a mitral valve and in the heart is removed enough, ascending aorta interception is canceled, and suture closing of the cardiotomy part is carried out thoroughly. Up-and-down vena-cava interception is canceled, an extracorporeal circulation flow is lowered, and extracorporeal circulation will be ended if the heart beat is enough. Since it is required to carry out manually to some extent and ** is after the end of mind operation, a way person and an operation assistant can enforce the separating operation from extracorporeal circulation.
[0065]The serious trouble under <safety measures to aeration> extracorporeal circulation enforcement has the aeration in a circuit. Especially when the blood reservoir of an enclosed type is used, since there is a danger of sending into a patient's artery if air is not removed promptly, it is a problem. The mixing part of air is an upstream negative pressure side from a pump. Therefore, it is important not to establish an unnecessary port in the negative pressure side. The terminal area of a circuit also needs a device from which it does not separate simply. Even if satisfactory in the circuit itself, air may be drawn in a blood removal pipe from the inside of the heart. Therefore, interception of up-and-down vena cava must be made into a positive thing.
[0066]A pump is controlled and inhaled and **** is prevented so that it may not become negative pressure with excessive inflow part circuit internal pressure. Even if it performs these safety measures, in consideration of a possibility that air will mix, a security apparatus is established further. The mixed air is detected by the bubble detection function of an ultrasonic flowmeter, sounds an alarm promptly, lowers the number of rotations of a pump, and reduces a flow. However, a stop is not carried out. Since a stop of a pump means circulation interception, the easy pump stop cannot say it as suitable correspondence. If the sensor of air detection is attached also to a filter and air accumulates more than fixed, a pump will be stopped promptly. The port of air extraction is established in the upper bed of the filter, a suction circuit is connected beforehand, and it usually intercepts. If air is detected by a bubble detection function or air accumulates in a filter, by automatic or manual operation, the interception to a suction circuit will be canceled and air will be removed outside a circuit. Also to a blood reservoir, an air extraction port is established in an upper bed, and it escapes from air if needed.
[0067]
[Effect of the Invention]According to this invention, when a blood reservoir has a capacity regulation means and a capacity capacity detection means, control of extracorporeal circulation

is easy and the extracorporeal circulation device with which the burden of equipment operation was eased can be provided. Automation of equipment operation is also attained. furthermore -- since a device can be safely operated even if it makes high the amount of driving flow of a blood pump by controlling a blood reservoir and a blood pump collectively -- low -- invasion extracorporeal circulation becomes possible.

[Translation done.]